REMARKS

Claims 10-21 are pending. The Applicants respectfully request the Examiner to reconsider the rejections in view of amendments to the claims now presented and the following remarks:

Claims 1-9 are now cancelled

The Applicants respectfully submit that the double patenting rejections, as well as objections set forth by the Examiner, are now moot since claims 1-9 are now cancelled.

Rejections under 35 USC §112, paragraph 1

The Examiner has alleged that the subject matter of claims 10-13 and 18-19 is not enabled under 35 USC §112 ¶1 in view of the written description.

The Applicants respectfully point out the purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. MPEP §2164. If a statement of utility in the specification contains within it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 USC §112 ¶1 is satisfied. MPEP §2164.01(c). For example, it is not necessary to specify the dosage or method of use if it is known to one skilled in the art that such information could be obtained without undue experimentation. If one skilled in the art, based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation, this would be sufficient to satisfy 35 USC §112 ¶1.[1] The Applicants need not demonstrate that the invention is completely safe. *See also*, MPEP §2107.01 and §2107.03.

[1] That some experimentation is required to practice the claimed invention is permissible, so long as it is not undue. Atlas Powder Co. v. E.I. DuPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413.

Introduction

The Applicants wish to begin by stating that chromanol glycosides described by the Applicants are generally amphiphilic molecules with extremely high water solubility (about 100 g/100 ml) *and* very high solubility in oil. Chromanol glycosides of the present invention are basically water soluble vitamin E derivatives endowed with high affinity for lipids.[2] Chromanol glycosides according to this invention, unlike the conventional vitamin E derivatives which are insoluble or sparingly soluble in water, retain the high affinity for lipids even when dissolved in water and exhibit excellent pharmacokinetic properties of percutaneous absorbency and cell membrane permeability.[3] The Applicants particularly demonstrate in the Examples, using models well-accepted in the art, that chromanol glycosides are suitable for external use, similar to vitamin E, but indeed possesses superior properties for the treatment of dermatological conditions. Specifically, the chromanol glycosides eliminate oxygen free radicals generated on and in skin cells by ultraviolet light, and effectively represses the otherwise consequential production of cytokines. Moreover, chromanol glycosides activate fibroblasts, for example, that synthesize collagen as a matrix component of the form of the skin. The Applicants also demonstrate the lack of toxicity issues associated with dermatological agents of the present invention.

Since the Applicants' chromanol glycosides are related to vitamin E and nontoxic - one of skill in the art would reasonably expect the administration thereof to be relatively straightforward. Particularly, as stated by the Applicants, compositions of chromanol glycosides can be percutaneously administered to a target site in the form of a liquid preparation such as lotion, suspension, or emulsion, in the form of a semi-solid preparation such as gel, cream, or ointment, or a solution. The form of preparation and the mode of administration may be properly selected by a physician to suit the age, sexuality, constitution, symptom, and time of treatment of each of the patients. Specification, p.18, line 17, *et seq.*

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[2] *See*, page 17 of the Specification. Chromanol glycoside is obtained by substituting an alcohol for the phytyl group at the 2 position of the chroman ring of α-tocopherol (vitamin E) and further linking a saccharum to the alcohol. *See*, page 3, line 9, *et seq.*, of the Specification.

[3] Chromanol glycoside also demonstrates significantly improved stability, e.g., thermal stability and pH stability compared with vitamin E (tocopherol), Trolox®.

a. The subject matter of claims 10-13

The Applicants wish to particularly point out that claims 10-13 now encompass specific methods of treating inflammation comprising administering an effective amount of a composition of a chromanol glycoside referred to as a dermatological agent. Although chromanol glycoside has not previously been employed to treat inflammation, the Applicants nevertheless demonstrate that chromanol glycosides are suitable for external use, similar to vitamin E, but indeed demonstrate superior properties for the treatment of inflammation. The Applicants particularly demonstrate, for example, that chromanol glycosides significantly improved the survival ratio of fibroblast cells after irradiation with UV as shown in Table 1. It is moreover unambiguous from the results presented in Table 2 to one skilled in the art that chromanol glycoside demonstrated a preventing effect in the production of IL-α (cytokine) and proved to be effective in controlling dermatological inflammatory conditions.[4] Furthermore, at page 29 of the Specification, the Applicants demonstrate the lack of toxicity issues associated with dermatological agents of the present invention. Accordingly, the Applicants respectfully submit that one of skill in the art would reasonably expect that undue experimentation is not required to administer an effective amount of a chromanol glycoside to ameliorate cutaneous inflammation. The Applicants therefore respectfully request the Examiner to withdraw the rejection of claims 10-13 under 35 USC §112, paragraph 1.

b. The subject matter of claims 18-19

The Applicants wish to particularly point out that claims 18-19 now encompass specific methods of preventing the formation of wrinkles and sags caused by ultraviolet light comprising administering an effective amount of a composition of a chromanol glycoside. Although chromanol glycoside has not previously been employed for this purpose, the Applicants nevertheless demonstrate that chromanol glycosides are suitable for external use, similar to vitamin E, but indeed demonstrate superior properties indicative for the preventing the formation of wrinkles and sags caused by ultraviolet light.

[4] The Examiner is respectfully referred to pages 22-26 of the Specification.

Fibroblasts synthesize collagen as a matrix component of the form of the skin. Chromanol glycosides are demonstrated by the Applicants to effectively activate fibroblasts.[5] It is particularly noted from Table 4 that the addition of a chromanol glycoside conferred a significantly discernible stimulation of fibroblasts. Accordingly, the Applicants respectfully submit that one of skill in the art would reasonably expect that undue experimentation is not required to administer an effective amount of a chromanol glycoside to ameliorate the formation of wrinkles and sags caused by ultraviolet light. The Applicants therefore respectfully request the Examiner to withdraw the rejection of claims 18-19 under 35 USC §112, paragraph 1.

Rejections under 35 USC §112, paragraph 2

The Examiner has alleged that the subject matter of claims 10-21 is indefinite under 35 USC §112 ¶2.

The Applicants have amended the claims to address the issues raised by the Examiner. Particularly, the parentheses are now removed from claims 10, 12, 14, 16, 18, and 20. Further, "x" as recited in the claims is now changed to "X" as used in formula (1). The Examiner's rejections to claim 7 should now be moot since the claim is cancelled. The typographical error "allowing" in claim 14 now reads "allaying". See, e.g., Specification p.27, lines 18-23; p.31, lines 26-27. Claims 16 is now amended to refer to "whitening" to refer to reducing pigmentation, for example, otherwise caused by UV light. Claims 20 is now amended to refer to "promoting growth". *See*, e.g., p.27 of the Specification.

Accordingly, the Applicants respectfully request the Examiner to withdraw the rejections under under 35 USC §112, paragraph 2.

Rejections under 35 USC §§102 and 103

The Applicants respectfully submit that the rejections under Title 35 USC §§102 and 103 set forth by the Examiner are now moot since claims 1-9 are now cancelled.

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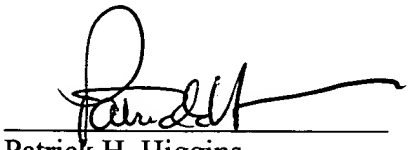
[5] The Examiner is respectfully referred to page 27, line 24 to page 29, line 9 of the Specification.

For all the foregoing reasons, the Applicants submit that claims 10-21 are in condition for allowance. Early action toward this end is courteously solicited. *The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution*.

A check in the amount of $930.00 to cover the cost of the three-month extension is enclosed. The Commissioner is authorized to charge any deficiency or credit any overpayment in connection herewith to Deposit Account No. 13-2165.

Respectfully submitted,



Patrick H. Higgins
Reg. No. 39,709
Attorney for Applicants

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MATHEWS, COLLINS, SHEPHERD & McKAY, P.A.
100 Thanet Circle, Suite 306
Princeton, New Jersey 08540-3662
Telephone: (609) 924-8555
Telecopier: (609) 924-3036